

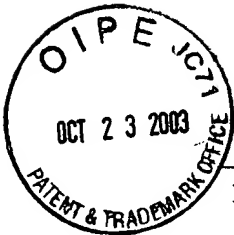


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EXHIBIT 1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wortzman, et al

Serial No. 09/864,083

Filed: May 23, 2001

Art Unit: 1614

Examiner: Vickie Y. Kim

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE
TREATMENT OF PIGMENTATION
DISORDERS AND METHODS FOR
THEIR MANUFACTURE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION

1. I, Philip J. Gordon, am a named inventor of the above-referenced patent application. I am additionally the President of Concept Laboratories located at 680 North Glenville Drive, Richardson, Texas.

2. My laboratory employee prepared samples of Examples 100B and 100C as described in United States Patent No. 5,980,871. Both samples were prepared to total 500 grams and were adjusted to reach a pH of 7.5 in accordance with the procedure within the aforementioned patent.

3. Example 100B of United States Patent No. 5,980,871, which included magnesium ascorbyl phosphate, when prepared in accordance with the instructions provided by the patent, resulted in a white/off white, low viscosity lotion that appeared to be aerated.

4. The prepared samples of Example 100B were placed in a stability oven at various temperatures which produced the following stability results:

<u>Temperature</u>	<u>Start Date</u>	<u>End Date</u>	<u>Comments</u>
45°C	8/27/03	9/11/03	Sample browning and separating at surface.
40°C	8/27/03	9/11/03	Sample browning at surface.
45°C	8/27/03	9/17/03	Separation, flocculation and browning at surface.
40°C	8/27/03	9/17/03	Separation, flocculation and browning at surface.

5. In my opinion, Example 100B of United States Patent No. 5,980,871, when prepared in accordance with the instructions provided by the patent, does not represent a viable cosmetic formulation due to its discoloration, separation and flocculation at 40°C after only two weeks which indicates an unstable formulation (See photograph, attached as Exhibit A).

6. Example 100C of United States Patent No. 5,980,871, which included hydroquinone, when prepared in accordance with the instructions provided by the patent, resulted in a reddish/brown, medium viscosity lotion that appeared to be aerated.

7. The prepared samples of Example 100C were placed in a stability oven at various temperatures which produced the following stability results:


<u>Temperature</u>	<u>Start Date</u>	<u>End Date</u>	<u>Comments</u>
45°C	8/27/03	9/11/03	Sample graying at surface.
40°C	8/27/03	9/11/03	Sample graying at surface.
45°C	8/27/03	9/17/03	Sample graying at surface.
40°C	8/27/03	9/17/03	Sample graying at surface.

8. In my opinion, Example 100C of United States Patent No. 5,980,871, when prepared in accordance with the instructions provided by the patent, suggests that the hydroquinone rapidly degrades due to the high pH (7.5) of the formula. Example 100C appears to be fluffy and not smooth. Further, Example 100C is not a good cosmetic emulsion due to the color instability after two weeks at 40°C (See photograph, attached as Exhibit B), further having an initial color of brown, which may be due to hydroquinone degradation.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Dated: 10/23/03


Philip J. Gordon